

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: AVANDIA MARKETING, SALES
PRACTICES AND PRODUCTS LIABILITY
LITIGATION**

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**MDL No. 1871
07-md-01871-CMR**

**THIS DOCUMENT RELATES TO ALL
ACTIONS**

**FIFTH REPORT AND RECOMMENDATION OF
THE SPECIAL DISCOVERY MASTER AS TO
THE DEPOSITION PROTOCOL AND OCEANS DATABASE**

Pretrial Order No. 28 sets forth the procedures regarding discovery disputes and directs the parties first to present discovery disputes to the Special Discovery Master for informal mediation efforts. On May 6, 2009, through a letter by its counsel, GSK brought to the attention of the Special Discovery Master a discovery dispute among the parties as to interpretation of the phrase “home district” in Pretrial Order No. 38 (Deposition Protocol) and the appropriate location for plaintiffs’ depositions. On May 8, 2009, the PSC responded via letter, expressing its position on this issue. On May 12, 2009, a conference was held with the Special Discovery Master to attempt to resolve the parties’ differences on this issue. Thereafter, the parties presented their arguments in briefing memorandum submitted to the Special Discovery Master on May 19, 2009. As the parties were unable to reach agreement on this issue, the Special Discovery Master submits this Report and Recommendation regarding the disputed issue.

In addition, in an April 13, 2009 letter, the PSC brought to the attention of the Special Discovery Master a discovery dispute regarding production of GSK’s OCEANS database of

adverse drug events. GSK responded to the PSC's letter and the PSC submitted a supplemental letter on April 27, 2009. A teleconference was held on April 28, 2009 and the issue was further discussed at a conference with the Special Discovery Master on May 12, 2009. The parties submitted additional briefing memorandum to the Special Discovery Master on May 19, 2009. As the parties were unable to reach agreement on this issue, the Special Discovery Master also addresses the OCEANS database issue in this Report and Recommendation.

I. DEPOSITION PROTOCOL

PTO No. 38 provides that "depositions of plaintiffs will take place in each plaintiff's *home district*." PTO No. 38, § II.F.1 (emphasis added). GSK contends that "the home district is the district where the plaintiff voluntarily chooses to file his or her action." Letter of Christopher W. Wasson at 1 (May 6, 2009). Plaintiffs argue that "home district" refers to "the district in which a deponent resides, not the district in which a given plaintiff filed his or her case." Letter of Joseph F. Roda at 1 (May 8, 2009). As set forth below, the Special Discovery Master recommends that the Court adopt plaintiffs' interpretation of "home district."

In support of its position, GSK relies on non-MDL cases in which courts (including this one) have held that a plaintiff must make himself available for deposition in the district in which he has brought suit. *See, e.g., Harris v. NCO Fin. Sys.*, No. 07-5546, 2009 U.S. Dist. LEXIS 15040, at *3 (E.D. Pa. Feb. 25, 2009) (Ludwig, J.); *McClain v. Camouflage Assocs.*, No. 93-0994, 1994 U.S. Dist. LEXIS 3676, at *4 (E.D. Pa. Mar. 25, 1994) (Hutton, J.). GSK also argues that, if it is required to take plaintiffs' depositions throughout the country, it will have trouble meeting the Court's strict discovery deadlines.

Plaintiffs claim that a plain reading of PTO No. 38 demonstrates that “home district” refers to each plaintiff’s district of residence. In support of this reading of the provision, plaintiffs point to another paragraph in Section II.F, which provides that “the deposition of an expert witness shall take place in the expert witness’ home district.” PTO No. 38, § II.F.2. As plaintiffs correctly note, expert witnesses do not file lawsuits and thus, “home district” in Section II.F.2 must refer to the district in which each expert resides. Plaintiffs argue that, by the same token, “home district” in Section II.F.1, the provision at issue here, must also refer to the district in which each plaintiff resides. Plaintiffs also point out that Section II.F.4 provides that depositions of GSK’s current or former employees may take place in Philadelphia “or in the current or former employees’ home district.” *Id.* § II.F.4. Again, in this context, “home district” could only refer to the district of residence for GSK’s employees; thus, plaintiffs argue, “home district” in Section II.F.1 also must refer to each plaintiff’s district of residence.

We believe that plaintiffs’ interpretation of “home district” in the PTO is the correct one. The repeated use of “home district” to refer to the location for depositions of plaintiffs, expert witnesses, and GSK’s employees convinces us that the parties intended “home district” to mean the district in which the deponent resides. *Cf. Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007) (“A standard principle of statutory construction provides that identical words and phrases within the same statute should normally be given the same meaning.”). Thus, the Special Discovery Master recommends that PTO No. 38 be interpreted to require that plaintiffs be deposed in the district in which they reside.

Although the Special Discovery Master recommends adoption of plaintiffs’ reading of PTO No. 38, it must be noted that there is well-established authority for the proposition that a plaintiff, by choosing a particular forum in which to file suit, consents to having his deposition taken

in that district. *See, e.g.*, 8A WRIGHT, MILLER & MARCUS, FEDERAL PRACTICE AND PROCEDURE § 2112, at 75 (2d ed. 1994 & Supp. 2008). Moreover, even where plaintiff contends that he had no choice but to file in the selected forum, the same rule typically applies. *See, e.g., Hart v. Simons*, 29 F.R.D. 146, 147 (E.D. Pa. 1961) (Van Dusen, J.). The rule does, however, contain exceptions, such as when plaintiff can show “unreasonable hardship or the presence of exceptional circumstances.” *Id.* GSK points out that the various plaintiffs deliberately filed in this District to obtain certain advantages in the litigation and with full knowledge that they would be expected to travel to Philadelphia.

At a conference with counsel on May 12, 2009, the Special Discovery Master initially indicated that he would recommend that the PTO be changed so that depositions of plaintiffs take place in Philadelphia, except in cases of unreasonable hardship to the plaintiff. These recommendations were based on two facts: (1) the cases were filed in the Eastern District; and (2) taking depositions in the district in which the deponent resides would likely result in delays that would make it more difficult to meet the schedule that has been adopted by the Court and frustrate the goal of promoting efficient conduct of multidistrict litigation.

Since that meeting, the Special Discovery Master has reviewed the briefs submitted by the parties and further considered the issue. The Special Discovery Master concludes that the deposition of plaintiffs should take place in the home district of the deponent, *i.e.*, the district in which the deponent resides. The reasons for this are: (1) the compelling language of the PTO itself;^{*}

^{*} The fact that there was direct filing in the MDL in this District is a consideration, but is not determinative with respect to the place where the deposition is to be taken. *See also* FED. R. CIV. P. 26(c)(1)(B).

(2) many of the deponents are ill and it would be a hardship for them to travel to the Eastern District for their depositions; for those not ill, such travel also would be a hardship because the travel time would result in loss of work and compensation, as well as the absence of family support, which can be traumatic for an unsophisticated deponent; and (3) the travel schedules of the lawyers involved are already so extensive in this case that having them travel to the residence of the deponent should pose no particular hardship or obstacle to efficiency.

In sum, the Special Discovery Master recommends that home district as used in PTO No. 38 should not be changed and should be interpreted to mean the district in which the deponent resides.

II. OCEANS DATABASE

Plaintiffs seek discovery of GSK's OCEANS database of adverse drug events ("ADEs") in its entirety. GSK has not objected to producing the portion of its OCEANS database containing cardiovascular and neurovascular ADEs. The PSC argues, however, that discovery of the entire OCEANS database is necessary for the plaintiffs' experts to adequately opine on GSK's pharmacovigilance activities and to address plaintiffs' legal claims. Pls.' OCEANS Br. at 2.

In its initial letter brief, PSC offered a number of reasons for seeking the discovery of the entire OCEANS database. These are:

1. In pharmaceutical post-marketing surveillance, the drug seller has a duty to monitor all information from the field about adverse reactions, monitor adverse interactions with other drugs, and identify groups of consumers at special risk who would benefit from a special warning or medical monitoring. The PSC asserts it cannot ascertain whether, in the face of adverse

information, GSK's actions and the timing of those actions were reasonable unless the PSC sees all the OCEANS data that GSK saw.

2. The PSC's analysis of OCEANS data when compared with other discovery of GSK's pharmacovigilance, regulatory, and sales and marketing practices may also reveal whether GSK engaged in a pattern or practice of illegally promoting off label uses, touting unapproved benefits of its products, and downplaying or concealing known risks. Therefore, discovery of all OCEANS data associated with Avandia is required so that a comparison may be made for inconsistencies and inaccuracies in GSK's reporting. Further, without such discovery, PSC contends that it has no way to verify whether or not GSK disclosed all required OCEANS data to the FDA.

3. Discovery of all adverse events associated with Avandia is essential to analyze risk analysis.

4. Complete Avandia ADE data is needed so that prescribing physicians can be queried on the extent of their reliance on the package insert and whether they would have prescribed Avandia if they had known additional ADE data.

5. In the routine course of business, GSK analyzes the same safety data as requested by the PSC. Therefore OCEANS data and the resulting analysis form an integral part of GSK's operation.

6. GSK's burden in producing the full OCEANS data is outweighed by the value of the discovery sought in relation to the claims or defenses raised and by the potential collective recovery for plaintiffs.

At the meeting on May 12, 2009, the PSC for the first time included an additional argument: that PSC's experts must see all of the adverse events data in order to perform a proper analysis. In its brief of May 19, 2009, PSC refined its arguments to stress two points: (1) the OCEANS data was needed for PSC's experts to undertake the same type of analysis that the experts would perform in a non-litigation setting; and (2) the OCEANS data directly related to plaintiffs' legal claims for negligence, strict liability, breach of warranty, and fraud.

GSK argues that adverse event reports not relating to the conditions at issue in this litigation are not relevant and therefore not properly subject to discovery. Put another way, GSK argues that the data sought by PSC is not within the scope of discovery contemplated by Rule 26(b)(1) of the Federal Rules of Civil Procedure. Rule 26 authorizes "discovery regarding any non-privileged matter that is relevant to any party's claim or defense." FED. R. CIV. P. 26(b)(1). While plaintiffs broadly allege negligence, breach of warranty, strict products liability, and fraud, plaintiffs' alleged injuries *specifically* involve adverse cardiovascular and neurovascular events such as congestive heart failure and stroke. As reflected in plaintiff Andrew Walker's complaint, submitted by the PSC with its OCEANS memorandum, plaintiffs contend in their negligence claim that GSK was negligent in failing "to adequately warn of the increased risk of serious cardio-vascular events" and in selling Avandia when it allegedly was not safe "because it caused serious cardio-vascular events." Compl., ¶¶ 36-37. Plaintiffs further contend that GSK breached express and implied warranties because plaintiffs' use of Avandia allegedly caused or contributed to plaintiffs' adverse cardiovascular and neurovascular events. *Id.* ¶ 55. Plaintiffs also contend that GSK is strictly liable for selling an allegedly defective product that caused plaintiffs' adverse cardiovascular and neurovascular events. *Id.* ¶ 64. Thus, plaintiffs' claims specifically involve alleged wrongful conduct by GSK leading to plaintiffs' adverse cardiovascular and neurovascular events.

As Judge Golden of this Court recently noted, “Rule 26 reflects, *inter alia*, the principle that ‘discovery is not intended as a fishing expedition permitting the speculative pleading of a case first and then pursuing discovery to support it.’” *Santer v. Teachers Ins. & Annuity Ass’n*, No. 06-CV-1863, 2008 U.S. Dist. LEXIS 21767, at *7 (E.D. Pa. Mar. 19, 2008) (quoting *Zuk v. Eastern Pa. Psychiatric Inst.*, 103 F.3d 294, 299 (3d Cir. 1996)). Moreover, plaintiffs “cannot have free reign to discover defendants’ documents solely for the purpose of establishing corporate state of mind.” *Id.* at *13. Where a plaintiff cannot connect information contained in the documents he seeks to his particular claims, discovery of the documents is not warranted. *Id.* at *25. As Judge Golden noted, where this is the case, the court is “left to assume that the only purpose for [plaintiff’s] request is the hope that it might uncover some heretofore unknown corporate misconduct.” *Id.* at *26; *see also Professional Recovery Servs., Inc. v. General Elec. Capital Corp.*, No. 06-2829, 2009 U.S. Dist. LEXIS 3889, at *13 (D.N.J. Jan. 15, 2009) (“To cast a wide net for discovery of information in the hopes that something of use may come back is the essence of a fishing expedition precluded by the rule of proportionality” in Rule 26(b)).

The same appears to be the case here. Plaintiffs’ claims are all based on their alleged cardiovascular or neurovascular injuries. Plaintiffs contend that GSK sold an unreasonably dangerous medication without adequate warnings, leading to plaintiffs’ cardiovascular or neurovascular injuries. GSK has not objected to producing information from its OCEANS adverse drug events database relating to such events. The only purpose that plaintiffs can have for seeking the remainder of the OCEANS data regarding adverse drug events *other than* cardiovascular or neurovascular events “is the hope that it might uncover some heretofore unknown corporate misconduct.” *Santer*, 2008 U.S. Dist. LEXIS 21767, at *26; *cf. Skibniewski v. American Home Prods.*

Corp., No. 99-0842-CV-W-FJG, 2004 U.S. Dist. LEXIS 31014, at *22-*25 (W.D. Mo. Apr. 1, 2004) (excluding evidence of adverse events that were not similar to plaintiff's claimed injury).

The cases cited by the PSC are inapposite. For example, while plaintiffs cite *Brown v. James*, No. 03-0631, 2009 U.S. Dist. LEXIS 22428 (M.D. Pa. Mar. 18, 2009), for the proposition that discovery may be had of any information "relevant to the general subject matter of the action," the court in *Brown* relied on pre-2000 cases that, in light of the 2000 amendments to Rule 26, are no longer good law. *Id.* at *6-*7. As noted above, Rule 26 now limits discovery to "matter that is relevant to *any party's claim or defense*." FED. R. CIV. P. 26(b)(1) (emphasis added). Here, plaintiffs' claims all relate to their alleged cardiovascular or neurovascular injuries. Documents involving other alleged adverse events from Avandia simply are not within the scope of discovery under Rule 26.

Moreover, we are not persuaded by the PSC's argument that, if plaintiffs' experts cannot review all of the adverse events listed in the OCEANS database, they will be subject to challenge under *Daubert* because they would not have relied on the same information that they would have if analyzing the data in a non-litigation setting. For one thing, "*Daubert* makes clear that the factors it mentions do *not* constitute a 'definitive checklist or test.' . . . It made clear that its list of factors was meant to be helpful, not definitive. Indeed, those factors do not all necessarily apply even in every instance in which the reliability of scientific testimony is challenged." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150-51 (1999) (emphasis in original). Thus, the fact that plaintiffs' experts will examine a smaller set of data than they allegedly would review in a non-litigation setting is not dispositive of the admissibility of their expert opinions. For another, we seriously doubt that GSK, after objecting to production of the entire OCEANS database, will contend that plaintiffs' experts are not qualified to testify because they did not examine the entire OCEANS database.

The Special Discovery Master recommends that plaintiffs' request for discovery of GSK's entire OCEANS database be denied.

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A proposed Order reflecting the Special Discovery Master's recommendations accompanies this Report and Recommendation. Pursuant to PTO Nos. 8 and 28, any party seeking to prevent this Report and Recommendation from taking effect must file with the Court an appeal in the form of a motion with the Court within ten (10) calendar days from the date this Report and Recommendation is filed with the Court, setting forth the relief requested. If no appeal is filed with the Court within the ten (10) day period, this Report and Recommendation will be deemed to be accepted by all parties and the Court will enter an Order accordingly.

Dated: May 21, 2009

/s/ Jerome J. Shestack
Jerome J. Shestack, Special Discovery Master

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CERTIFICATE OF SERVICE

I, Bruce P. Merenstein, hereby certify that on May 21, 2009, I caused to be electronically filed the foregoing **Fifth Report and Recommendation of the Special Discovery Master As to the Deposition Protocol and OCEANS Database**. Through the Court's ECF system, this document is available for viewing and downloading.

/s/ Bruce P. Merenstein

Bruce P. Merenstein